

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
CENTRAL DIVISION**

**NOVARTIS PHARMACEUTICALS
CORPORATION,**

Plaintiff,

v.

Case No. 2:24-cv-04131-MDH

**ANDREW BAILEY, in his official capacity as
ATTORNEY GENERAL OF THE STATE OF
MISSOURI; JAMES L. GRAY, in his official
capacity as President of the Missouri Board of
Pharmacy; CHRISTAN S. TADRUS, in his
official capacity as Vice-President of the
Missouri Board of Pharmacy; and DOUGLAS
R. LANG, ANITA K. PARRAN, COLBY
GROVE, TAMMY THOMPSON, and DARREN
HARRIS, in their official capacities as members
of the Missouri Board of Pharmacy,**

Defendants.

v.

**MISSOURI HOSPITAL ASSOCIATION,
And MISSOURI PRIMARY CARE
ASSOCIATION,**

Intervenors

ORDER

Before the Court is Plaintiff's Motion for Preliminary Injunction. (Doc. 3). Plaintiff has filed its suggestions in support for its motion (Doc. 9) and State Defendants have filed their suggestions in opposition. (Doc. 32). Plaintiff has replied (Doc. 35) and the matter is fully briefed before the Court. This issue is now ripe for adjudication. For reasons herein, Plaintiff's motion is **DENIED.**

BACKGROUND

This case arises out of Senate Bill (“S.B.”) 751 which created protections to the delivery of 340B drugs to contract pharmacies on behalf of “covered entities”. Section 340B incentivizes pharmaceutical manufactures to provide qualified health care providers, referred to as “covered entities,” with pricing discounts on certain drugs prescribed to individuals and families whose income falls below the federal poverty level. Covered entities have contracted with outside pharmacies or “contract pharmacies,” for the distribution and dispensation of 340B drugs. S.B. 751 protects hospitals, federal qualified health centers (“FQHC”), and their patients from drug manufacturers’ restrictions on the number of contract pharmacies a hospital or FQHC can use and still receive discount pricing under 340B plan. Plaintiff is a pharmaceutical corporation organized in Delaware with its principal place of business in New Jersey. State Defendants are all residents of Missouri that are responsible for administering and enforcing the provisions of S.B. 751. Intervenor Missouri Hospital Association and Missouri Primary Care Association are Missouri, not-for-profit member organizations.

Plaintiff alleges three Counts seeking declaratory relief that S.B. 751 is unconstitutional and injunctive relief barring enforcement of S.B. 751. Count I alleges S.B. 751 is preempted by federal patent and drug exclusivity laws under the Supremacy Clause. Count II alleges S.B. 751 is preempted by federal 340B law under the Supremacy Clause and Count III alleges S.B. 751 violates the dormant Commerce Clause.

STANDARD

A preliminary injunction is an extraordinary remedy never awarded as of right. *Munaf v. Geren*, 553 U.S. 674, 688, 128 S. Ct. 2207, 2217, 171 L. Ed. 2d 1 (2008). In each case, courts “must balance the competing claims of injury and must consider the effect on each party of the

granting or withholding of the requested relief.” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24, 129 S. Ct. 365, 376, 172 L. Ed. 2d 249 (2008) (quoting *Amoco Prod. Co. v. Vill. Of Gambell, AK*, 480 U.S. 531, 542, 107 S. Ct. 1396, 1401, 94 L. Ed. 2d 542 (1987)). “In exercising their sound discretion, courts of equity should pay particular regard for the public consequences in employing the extraordinary remedy of injunction.” *Id.* (quoting *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 311, 102 S. Ct. 1798, 1803, 72 L. Ed. 2d 91 (1982)).

Courts in the Eighth Circuit consider four factors when deciding whether to grant a preliminary injunction: (1) the movant’s probability of success on the merits; (2) the threat of irreparable harm to the movant; (3) the balance of movant’s harm and the injury an injunction could inflict on other parties; and (4) the public interest. *Heartland Academy Community Church v. Waddle*, 335 F.3d 684 (8th Cir. 2003) (citing *Dataphase Systems, Inc. v. C L Systems, Inc.*, 640 F.2d 109 (8th Cir. 1981)); *see also Associated Producers Co. v. City of Independence, Mo.*, 648 F. Supp. 1255 (W.D. Mo. 1986).

DISCUSSION

I. Probability of Success on the Merits

“Since *Dataphase*, the Eighth Circuit has generally held that the likelihood of success on the merits is the most significant factor.” *Champion Salt, LLC v. Arthofer*, No. 4:21-cv-00755-JAR, 2021 WL 4059727, at *6 (E.D. Mo. Sept. 7, 2021) (citing *Barrett v. Claycomb*, 705 F.3d 315, 320 (8th Cir. 2013)). In a challenge to a federal statute, state statute, or other “government action based on presumptively reasoned democratic processes, the movant must show “a substantial likelihood of success on the merits[.]” *Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724, 731–32 (8th Cir. 2008) (en banc) (internal citations and quotations omitted). This burden requires the movant to demonstrate more than just a “fair chance” of success on the

merits. *Id.* This more rigorous standard “reflects the idea that governmental policies implemented through legislation or regulations developed through presumptively reasoned democratic processes are entitled to a higher degree of deference and should not be enjoined lightly.” *Id.*

Plaintiff argues S.B. 751 is unconstitutional based on preemption of federal patent and drug exclusivity laws; preempted by federal 340B laws; and that it violates the dormant Commerce Clause. The Court will review the likelihood of success on the merits of each claim.

a. Preemption of Federal Patent and Drug Exclusivity Laws

Plaintiff argues that requiring drug manufactures to offer the 340B discount on sales made through contract pharmacy arrangements, even during the market exclusivity periods under federal law, S.B. 751 operates as a state-mandated price cap. State Defendants argue that federal marketing exclusivity periods do not conflict preempt S.B. 751 as it does not adjust prices at which Plaintiff sells 340B drugs.

“Article VI of the Constitution provides that the laws of the United States ‘shall be the supreme Law of the Land; ... any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.’” U.S. Const. art. VI, cl. 2. State laws that conflict with federal law are “without effect.” *Cipollone v. Liggett grp., Inc.*, 505 U.S. 504, 516, 112 S.Ct. 2608, L.Ed.2d 407 (1992). Congress may preempt a state law through federal legislation, but where a federal statute does not refer expressly to preemption, Congress may implicitly preempt a state law. *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 376, 135 S.Ct. 1591, 191 L.Ed.2d 511 (2015). Congress may impliedly preempt state law “either through ‘field’ preemption or ‘conflict’ preemption.” *Id.* Conflict preemption exists where ‘compliance with both state and federal law is impossible,’ or where ‘the state law stands as an obstacle to the accomplishment and execution of the full purposes and

objections of Congress.” *Id.* (quoting *California v. ARC Am. Corp.*, 490 U.S. 93, 100, 101, 109 S.Ct. 1661, 104 L.Ed.2d 86 (1989)).

S.B. 751 by its plan language does not control the price to which 340B drugs are sold, as the federal 340B law governs in that aspect, but rather sets protection on the acquisition or delivery of 340B drugs to contract pharmacies. As Mo. Rev. Stat. § 376.414.2 states:

A pharmaceutical manufacturer, third-party logistic provider, or an agent or affiliate of such pharmaceutical manufacturer or third-party logistics provider, *shall not deny, restrict, or prohibit, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with, or otherwise authorized by, a covered entity to receive 340B drugs on behalf of the covered entity* unless such receipt is prohibited by the United States Department of Health and Human Services.

Id. (emphasis added). S.B. 751 makes no mention of exclusivity periods, patent terms, or even deals with pricing discounts. The 340B Program has specific enforcement measures that safeguards the prices at which manufactures can sell their patented drug while also complying with the provisions of the 340B program. Drug manufactures, such as Novartis opted in to the 340B program. *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F.4th 1136 (8th Cir. 2024), *cert. denied*, No. 24-118, 2024 WL 5011712 (U.S. Dec. 9, 2024) (“as a condition of participating in Medicaid, drug manufactures must opt into the 340B program by signing a form Pharmaceutical Pricing Agreement with the Secretary of HHS.”) The 340B program either includes the requirement that drug manufactures provide drugs covered by exclusivity periods to covered entities.

S.B. 751 explicitly states its protections apply only to the acquisition and delivery of 340B drugs. The 340B program is what determines and sets the discount on those drugs, and Plaintiff specifically opting in to provide those drugs at a discount price to those drugs covered by exclusivity periods to covered entities. As such the Court finds that the likelihood of success on

the merits for Count I is below the substantial likelihood of success standard necessary for a preliminary injunction.

b. Preemption by Federal 340B Laws

Plaintiff argues that S.B. 751 is preempted by the federal 340B statutes based on principles of both field preemption and conflict preemption. State Defendants argue that the Eighth Circuit in *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F.4th 1136 (8th Cir. 2024) has ruled a similar Arkansas statute was not field preempted or conflict preempted by federal 340B law.

Under Eighth Circuit precedent the 340B program is not “so pervasive ... that Congress left no room for the States to supplement it. *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F. 4th 1136 (8th Cir. 2024) at 1144 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947)). The Eighth Circuit reasoned that pharmacies have always been an essential part of the 340B program and Congress’s decision not to legislate the issue of pharmacy distribution indicates that Section 340B is not intended to preempt the field. *Id.* The practice of pharmacy is an area traditionally left to state regulation and that the case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest and has nonetheless decided to stand by both concept and to tolerate whatever tension there [is] between them.” *Id.* Further, the Eighth Circuit analyzed the difference between a state statute that ensures an oversight and enforcement scheme in promoting its protections for covered entities to distribute 340B compared to the federal 340B Program and its means for enforcement of discount prices. *Id.* The Eighth Circuit found that a statute which establishes enforcement for the distribution of 340B drugs and the federal 340B law’s enforcement scheme address two completely different issues and thus Congress did not intent to preempt the

field with its 340B legislation. Given the Eighth Circuit precedent for Plaintiff's argument, Plaintiff has not shown a substantial likelihood of success on the merits on Count II.

c. Violation of the Dormant Commerce Clause

Plaintiff asserts in Count III that S.B. 751 violates the dormant Commerce Clause as it is unlawfully extraterritorial, it has both a discriminatory intent and effect, and it excessively burdens interstate commerce. A state statute violates the dormant Commerce Clause if it (1) "clearly discriminates against interstate commerce in favor of in-state commerce," (2) "imposes a burden on interstate commerce that outweighs any benefits received," or (3) "has the practical effect of extraterritorial control on interstate commerce. *Grand Rivers Enters. Six Nations, Ltd. v. Beebe*, 574 F.3d 929, 942 (8th Cir. 2009).

1. Discriminates on Interstate Commerce

Plaintiff argues that S.B. 751 privileges in-state pharmacies while significantly burdening out-of-state drug manufacturers like Plaintiff. State Defendants argue that for purposes of the dormant Commerce Clause the correct analysis is looking at how S.B. 751 discriminates against out-of-state drug manufacturers compared to in-state drug manufacturers. State Defendant's claim there is no discrimination and thus no dormant Commerce Clause issue.

A state statute discriminates against interstate commerce if it accords "differential treatment of in-state and out-of-state economic interests that benefits the former and burdens the latter." *Jones v. Gale*, 470 F.3d 1261, 1267 (8th Cir. 2006). The dormant Commerce Clause is only implicated when the discrimination is between "substantially similar entities." *MDKC, LLC v. City of Kansas City*, No. 4:23-CV-00395-DKG, 2023 WL 6406403 at *7 (W.D. Mo. Oct. 2, 2023) (quoting *Dep't of Revenue of Ky. v. Davis*, 553 U.S. 328, 342, 128 S. Ct. 1801, 1811, 170 L. Ed. 2d 685 (2008)).

While Defendant cites many cases that show a similar comparison of comparing the same industry and comparing the effects of the in-state industry compared to the out-of-state industry for purposes of the dormant Commerce Clause analysis, this is not dispositive. The Court has found no case law that specifies that a dormant Commerce Clause analysis must be predicated on comparing the same industry and reviewing the effects simply from an in-state or out-of-state vantage point. A fundamental element of dormant Commerce Clause jurisprudence is the principle that “any notion of discrimination assumes a comparison of substantially similar entities.” *Dep’t of Revenue of Ky. v. Davis*, U.S. 328, 342 (2008). Therefore, the analysis must focus on substantially similar entities. However, Plaintiff has not shown how in-state pharmacies are substantially similar to out-of-state manufacturers. The Court finds that Plaintiff has not shown a substantial likelihood of success that S.B. 751 discriminates on interstate commerce.

2. Imposes a Burden on Interstate Commerce that Outweighs the Benefits

Plaintiff argues that the bargaining power favors in-state pharmacies and covered entities at the expense of out-of-state drug manufacturers, Plaintiff must contend with a patchwork of state laws, and the burdens will only increase as more states start to adopt similar laws. State Defendants argue that Plaintiff has not shown that S.B. 751 imposes a substantial burden on interstate commerce.

The court must analyze whether the burden imposed by the statute is excessive compared to the benefits. *Turtle Island Foods, SPC v. Thompson*, 725 F. Supp. 3d 963, 977 (W.D. Mo. 2024). The extent of the burden that will be tolerated will depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.” *Id.* (quoting *Ass’n to Pres. & Protect Loc. Livelihoods v. Town of Bar Harbor*, 721 F. Supp. 3d 56, 95 (D. Me. 2024)). But even so, “preventing state officials from enforcing a democratically adopted

state law in the name of the dormant Commerce Clause is a matter of ‘extreme delicacy’, something courts should do only ‘where the infraction is clear.’” *Id.*

The Court, reviewing the burdens listed by Plaintiff, cannot say those burdens are excessive compared to the local benefits. S.B. 751 assists in fulfilling the purpose of 340B to program to provide qualified health care providers, with pricing discounts on certain drugs prescribed to individuals and families whose income falls below the federal poverty level. Given the intent of the legislation, benefits sought, and the burdens listed the Court finds that there is not a substantial likelihood of success on the merits that S.B. 751 imposes a burden on interstate commerce that outweighs its benefits.

3. Extraterritorial Control on Interstate Commerce

Plaintiff argues that the practical discriminate effect of S.B. 751 is to directly regulate wholly out-of-state transactions between manufacturers and other private entities. State Defendants argue that S.B. 751 does not apply extraterritorially and even so S.B. 751 does not directly regulate transactions taking place wholly outside the state involving individuals having no connection with Missouri.

The Commerce Clause precludes the application of a state statute to commerce that takes place wholly outside of the state’s borders, whether or not the commerce has effects within the state. *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336, 109 S. Ct. 2491, 105 L.Ed.2d 275 (1989). However, there is no per se rule under the dormant Commerce Clause forbidding enforcement of state laws that have the practical effect of controlling commerce outside the state, when those laws do not purposely discriminate against out-of-state economic interests. *Nat’l Pork Producers Council v. Ross*, 598 U.S. 356, 143 S. Ct. 1142, 1159, 215 L. Ed. 2d 336 (2023). Missouri statutes,

absent express text to the contrary, apply only within the boundaries of the state and have no extraterritorial effect. *Tuttle v. Dobbs Tire & Auto Centers, Inc.*, 590 S.W.3d 307, 311 (Mo. 2019).

However, Plaintiff struggles to show how S.B. 751 purposely discriminates against out of state interests. First, there is a presumption that statutes passed in Missouri are not extraterritorial absent express test to the contrary. Second, the effects of S.B. 751 applies equally to any manufacturer enrolled in the 340B program regardless of their in-state or out-of-state operations. Further S.B. 751 does not purport to directly regulate transaction which occur wholly outside of Missouri but rather the delivery and acquisition of 340B drugs to contract pharmacies within the state. The Court cannot say Plaintiffs argument has a substantial likelihood of success on the merits. The Court finds that while Plaintiff may argue some likelihood of success, they have failed to show a substantial likelihood of success on the merits regarding Counts I, II, and III.

II. Irreparable Harm

Plaintiff argues regardless of if it complies with S.B. 751 it will face irreparable harm. Specifically, Plaintiff asserts if it does not comply with what it deems to be a preempted law it will be subject severe penalties including violations Missouri Merchandising Practices Act or even criminal liability. If Plaintiff does comply, it argues that there is no readily apparent mechanism to recover for contract pharmacies or covered entitles any 340B discounts given while under enforcement of S.B. 751 should it be found unconstitutional. Defendant argues that Plaintiff has not shown irreparable harm because the harm it alleges it will suffer are reparable.

“In order to demonstrate irreparable harm, a party must show that the harm is certain and great and of such imminence that there is a clear and present need for equitable relief.” *Novus Franchising, Inc. v. Dawson*, 725 F.3d 885, 895 (8th Cir. 2013) (quoting *Iowa Utils. Bd. v. Fed. Commc'ns Comm'n*, 109 F.3d 418, 425 (8th Cir.1996)). The plaintiff must show the harm is “not merely a ‘possibility’” but is likely to occur absent preliminary injunctive relief. *Morehouse*

Enterprises, LLC v. Bureau of Alcohol, Tobacco, Firearms & Explosives, 78 F.4th 1011, 1017 (8th Cir. 2023) (quoting *Tumey v. Mycroft AI, Inc.*, 27 F.4th 657, 665 (8th Cir. 2022)). In most instances, constitutional violations constitute irreparable harm. *See Powell v. Ryan*, 855 F.3d 899, 904 (8th Cir. 2017) (en banc). However, the assertion of a possible constitutional violation does not release plaintiffs from their burden of showing that irreparable harm is more than just a “mere possibility.” *See Sessler v. City of Davenport, Iowa*, 990 F.3d 1150, 1156 (8th Cir. 2021).

Here Plaintiff has failed to show that the harm is not merely a possibility but is likely to occur absent preliminary injunctive relief. Plaintiff’s claims of irreparable harm are all based on the premise that S.B. 751 is an unconstitutional law that will force Plaintiff to either be forced into compliance costing Plaintiff monetary damage or not adhere to the law and face potential penalties and criminal liability. However, Plaintiff’s harms are only a mere possibility depending on the constitutional status of S.B. 751. If S.B. 751 is constitutional than Plaintiff will not suffer any irreparable harm. The Court finds that Plaintiff has not showed that irreparable harm in this case would warrant an extraordinary remedy such as a preliminary injunction.

III. Balance of Equities

Plaintiff argues that its harm without a preliminary injunction exceeds the nonmovant’s likely harm with a preliminary injunction in place. State Defendants argue that prevent the State from enforcing constitutional restrictions is an irreparable harm; Plaintiff has not demonstrated irreparable harm; a preliminary injunction would be against the public interest; and Plaintiff is seeking to undermine a federal program developed to help institutions serve disadvantaged populations.

The balance of equities analysis examines the harm of granting or denying the injunction upon both of the parties to the dispute and other interested parties, including the public. *Dataphase*,

640 F.2d at 113. In doing so, courts consider the threat to each of the parties' rights that would result from granting or denying the injunction, the potential economic harm to the parties, and interested third parties, and whether the defendant has already taken remedial action. *Noodles Development, LP v. Ninth Street Partners, LLP*, 507 F. Supp. 2d 1030, 1038-39 (E.D. Mo. 2007). "Any time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers) (citation omitted); *see also 1-800-411- Pain Referral Service, LLC v. Otto*, 744 F.3d 1045, 1053-54 (8th Cir. 2014) (holding that in the context of a preliminary injunction, courts apply "a more rigorous threshold showing than th[e] ordinary preliminary injunction test" when the injunction would impede state law); *Planned Parenthood of Greater Texas Surgical Health Servs. v. Abbott*, 734 F.3d 406, 419 (5th Cir. 2013) ("When a statute is enjoined, the State necessarily suffers the irreparable harm of denying the public interest in the enforcement of its laws.").

As already discussed above, Plaintiff has failed to prove their harm is anything more than a mere possibility based on the constitutional status of S.B. 751. Whereas an order granting injunctive relief against S.B. 751 would be a form of irreparable injury to the state of Missouri. Additionally, granting the preliminary injunction would further cause injury to covered entities who would then be subject to policy changes on delivery of 340B drugs by drug manufacturers. The Court finds that the balance of equities tip in favor against granting the preliminary injunction.

IV. The Public Interest

Plaintiff argues that the public has a substantial interest in seeing that federal law is enforced and not bowing to state efforts to reset the metes and bounds of participation in the federal

healthcare programs. State Defendants argue that the public has an interest in permitting the State to enforce laws duly passed by the legislature.

An injunction is in the public interests if the public interest would be served by injunctive relief. *See Community of Christ Copyright Corp. v. Devon Park Restoration Branch of Jesus Christ's Church*, 613 F. Supp. 2d 1140, 1145 (W.D. Mo. 2009). Section 340B incentivizes pharmaceutical manufactures to provide qualified health care provides with pricing discounts on certain drugs prescribed to individual and families whose income falls below the federal poverty level. *Pharm. Rsch. & Manufacturers of Am. v. McClain*, 95 F.4th 1136, 1139 (8th Cir. 2024), *cert. denied*, No. 24-118, 2024 WL 5011712 (U.S. Dec. 9, 2024). S.B. 751 aims to create protections to the delivery of those drugs to those qualified health care providers. The legislature, by virtue of a democratic process, has created a law to protect delivery of 340B drugs under in support of the 340B federal program. The public has an interest in seeing the state enforces its law in tandem with the goal of helping enforce a federal program designed to benefit the public whose income falls below the federal poverty level. The Court finds that a preliminary injunction would be contrary to the public interest in this case.

CONCLUSION

In evaluating the motion for a preliminary injunction, the Court finds that Plaintiff has not shown a substantial likelihood of success on the merits. Plaintiff has not shown more than a mere possibility of irreparable harm, and both the balance of equities and the public interest would be served by denying the motion for preliminary injunction. As such, Plaintiffs Motion for a Preliminary Injunction is **DENIED**.

IT IS SO ORDERED.

DATED: February 24, 2025

/s/ Douglas Harpool
DOUGLAS HARPOOL
UNITED STATES DISTRICT JUDGE